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U.S. DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FILED
SEP 18 2019
CLERK, U.S. DISTRICT COURT
By _____ Deputy

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA	Criminal No.
v.	
DANIEL R. CANCHOLA, M.D. (01)	UNDER SEAL 3-19CR-473-E

INDICTMENT

The Grand Jury charges that:

General Allegations

At all times material to this indictment,

The Medicare Program

1. The Medicare Program ("Medicare") was a federally funded program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. The benefits available under Medicare were governed by federal statutes and regulations. The United States Department of Health and Human Services ("HHS"), through its agency, the Centers for Medicare and Medicaid Services ("CMS"), oversaw and administered Medicare. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."

2. Medicare was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b) and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).

3. Medicare programs covering different types of benefits were separated into

different program "parts." Part B of the Medicare Program was a medical insurance program that covered, among other things, medical services provided by physicians, medical clinics, laboratories and other qualified health care providers, such as office visits, minor surgical procedures, and laboratory testing, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers.

4. Physicians, clinics and other health care providers, including laboratories, that provided services to Medicare beneficiaries were able to apply for and obtain a "provider number." A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

5. A Medicare claim was required to contain certain important information, including: (a) the Medicare beneficiary's name and Health Insurance Claim Number ("HICN"); (b) a description of the health care benefit, item, or service that was provided or supplied to the beneficiary; (c) the billing codes for the benefit, item, or service; (d) the date upon which the benefit, item, or service was provided or supplied to the beneficiary; and (e) the name of the referring physician or other health care provider, as well as a unique identifying number, known either as the Unique Physician Identification Number ("UPIN") or National Provider Identifier ("NPI"). The claim form could be submitted in hard copy or electronically.

Medicare Part B Coverage and Regulations

6. CMS acted through fiscal agents called Medicare administrative contractors ("MACs"), which were statutory agents for CMS for Medicare Part B. The MACs were

private entities that reviewed claims and made payments to providers for services rendered to Medicare beneficiaries. The MACs were responsible for processing Medicare claims arising within their assigned geographical area, including determining whether the claim was for a covered service.

7. To receive Medicare reimbursement, providers had to make appropriate application to the MAC and executed a written provider agreement. The Medicare provider enrollment application, CMS Form 855A, was required to be signed by an authorized representative of the provider. CMS Form 855A contained certifications that the provider agreed to abide by the Medicare laws and regulations, including the anti-kickback statute, and that the provider "will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

Cancer Genomic Tests

8. Cancer genomic ("CGx") testing used DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. CGx testing was not a method of diagnosing whether an individual presently had cancer.

9. Medicare did not cover diagnostic testing that was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Title 42, United States Code, Section 1395y(a)(1)(A). Except for certain statutory exceptions, Medicare did not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint

or injury." Title 42, Code of Federal Regulations, Section 411.15(a)(1). Among the statutory exceptions Medicare covered were cancer screening tests such as "screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests." *Id.*

10. If diagnostic testing were necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare imposed additional requirements before covering the testing. Title 42, Code of Federal Regulations, Section 410.32(a) provided, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

11. Because CGx testing did not diagnose cancer, Medicare only covered such tests in limited circumstances, such as when a beneficiary had cancer and the beneficiary's treating physician deemed such testing necessary for the beneficiary's treatment of that cancer. Medicare did not cover CGx testing for beneficiaries who did not have cancer or lacked symptoms of cancer.

Telemedicine

12. Telemedicine provided a means of connecting patients to doctors by using telecommunications technology, such as the internet or telephone, to interact with a patient.

13. Telemedicine companies provided telemedicine services to individuals by hiring doctors and other health care providers. Telemedicine companies typically paid doctors a fee to conduct consultations with patients. In order to generate revenue, telemedicine companies typically either billed insurance or received payment from patients who utilized the services of the telemedicine company.

14. Medicare Part B covered expenses for specified telehealth services if certain requirements were met. These requirements included that (a) the beneficiary was located in a rural or health professional shortage area; (b) services were delivered via an interactive audio and video telecommunications system; and (c) the beneficiary was a practitioner's office or a specified medical facility – not at a beneficiary's home – during the telehealth consultation with a remote practitioner.

The Defendants and Related Entities

15. In or around the charged period, defendant **Daniel Canchola**, a resident of Flower Mound, Texas, was a licensed physician.

16. In or around the charged period, Company A and Company B were limited liability companies organized under the laws of the State of Florida purportedly providing telemedicine and staffing services.

17. In or around the charged period, Person A and Person B owned and operated Company A and Company B.

18. In or around the charged period, Laboratory A was a laboratory in Baton Rouge, Louisiana that, among other things, purportedly conducted CGx testing for Medicare beneficiaries.

19. In or around the charged period, Laboratory B was a laboratory in Monroe, Louisiana that, among other things, purportedly conducted CGx testing for Medicare beneficiaries.

The Fraudulent Scheme

Overview of the Scheme

20. **Daniel Canchola** unlawfully submitted and caused to be submitted false and fraudulent claims to federal health care benefit programs for prescriptions for CGx tests. Federal health care benefit programs paid millions of dollars on these false and fraudulent claims. These prescriptions, as **Daniel Canchola** knew and intended, were, among other things, not legitimately prescribed, not needed, not used, and induced through the payment and receipt of unlawful kickbacks and bribes.

21. Over the course of, and furtherance of, the fraudulent scheme, which began no later than in or about May 2018 and continued until in or about March 2019, the exact dates being unknown to the Grand Jury, **Daniel Canchola**, and others known and unknown to the Grand Jury, caused Laboratory A and Laboratory B to submit false and fraudulent claims to Medicare for CGx tests that were not legitimately prescribed, not needed, not used, and induced through the payment and receipt of unlawful kickbacks and bribes, in at least the approximate amount of $69 million, via interstate wire communication.

22. As the result of these false and fraudulent claims, Medicare made payments to Laboratory A and Laboratory B in at least the approximate amount of $13 million.

Object/Purpose of the Scheme

23. The object/purpose of the scheme was for **Daniel Canchola,** his co-conspirators Person A and Person B, and others known and unknown to the Grand Jury, to unlawfully enrich themselves by, among other things: (a) paying and receiving kickbacks and bribes in exchange for the referral of Medicare beneficiaries, CGx tests, and the accompanying prescriptions for CGx testing and other Medicare-required documents (collectively referred to as "doctors' orders") to Laboratory A and Laboratory B, without regard for the medical necessity of the prescribed CGx tests; (b) submitting and causing the submission via interstate wire communication of false and fraudulent claims to Medicare, through Laboratory A and Laboratory B, for CGx tests that were not medically necessary and not eligible for reimbursement. The false and fraudulent claims were for CGx tests that were not legitimately prescribed, not needed, not used, and induced through the payment and receipt of unlawful kickbacks and bribes.

Execution of the Scheme

24. **Daniel Canchola** falsely certified to Medicare that he would comply with all Medicare rules and regulations, and federal laws, including that he would not knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare and that he would comply with the Anti-Kickback Statute.

25. **Daniel Canchola** worked as an independent contractor for Person A and Person B. Specifically, **Daniel Canchola** contracted with Company A and Company B, through Person A and Person B, to sign doctors' orders for CGx testing that would be used to support claims to Medicare.

26. **Daniel Canchola** received unsigned prescriptions for CGx testing, which were transmitted from Person A, Person B, Company A, Company B, and others for **Daniel Canchola** to sign.

27. **Daniel Canchola** signed doctors' orders for CGx testing for Medicare beneficiaries (a) without seeing, speaking to, or otherwise communicating with or examining them, and (b) without determining their need for the CGx tests. **Daniel Canchola** was not treating the beneficiaries for which he signed doctors' orders for CGx testing for cancer or symptoms of cancer, and he did not use the test results in the treatment of beneficiaries.

28. **Daniel Canchola** created invoices to track the number of beneficiaries for whom he had signed doctors' orders for CGx testing. **Daniel Canchola** sent the invoices to Person A and Person B, through Company A and Company B, requesting approximately $30 per doctors' order.

29. Person A and Person B, through Company A and Company B, paid illegal kickbacks and bribes to **Daniel Canchola** in exchange for signing doctors' orders for CGx testing.

30. The Medicare beneficiaries for whom **Daniel Canchola** signed doctors' orders for CGx testing were targeted by telemarketing campaigns and at health fairs, and they were induced to submit to CGx testing regardless of medical necessity.

31. Over the course of the conspiracy, Laboratory A and Laboratory B billed Medicare for CGx tests prescribed and referred by **Daniel Canchola**, and purportedly provided to Medicare beneficiaries who resided in Dallas County, Texas.

32. In furtherance of the scheme, and to accomplish its purpose, the conspirators committed, and caused to be committed, the submission of the false and fraudulent claims reflected in Counts Two through Four.

COUNT ONE
Conspiracy to Commit Health Care Fraud and Wire Fraud
(Violation of 18 U.S.C. § 1349 (18 U.S.C. §§ 1347 and 1343))

33. The Grand Jury re-alleges and incorporates by reference all previous paragraphs as if fully alleged herein.

The Conspiracy

34. From in or about May 2018 and continuing to in or about March 2019, the exact dates being unknown to the Grand Jury, in the Dallas Division of the Northern District of Texas and elsewhere, **Daniel Canchola** did knowingly and willfully combine, conspire, confederate, and agree with Person A, Person B, and other persons known and unknown to the Grand Jury, to commit offenses against the United States, that is:

a. to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, said health care benefit program, in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347; and

b. to knowingly and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud, and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing the pretenses, representations, and promises were false and fraudulent when made, and for the purpose of executing the scheme and artifice, did knowingly transmit and cause to be transmitted by means of wire communication in interstate and foreign commerce, certain writings, signs, signals, pictures and sounds, in violation of Title 18, United States Code, Section 1343,

all in violation of 18 U.S.C. § 1349.

The Object/Purpose of the Conspiracy

35. The Grand Jury re-alleges and incorporates Paragraph 23 as a description of the object/purpose of the conspiracy.

The Manner and Means of the Conspiracy

36. In furtherance of the conspiracy and to accomplish its object/purpose, the methods, manners, and means that were used are described in paragraphs 20 through 32, and incorporated by reference as though set forth fully therein.

COUNTS TWO THROUGH FOUR
Health Care Fraud
(Violation of 18 U.S.C. §§ 1347 and 2)

37. The Grand Jury re-alleges and incorporates by reference all previous paragraphs as if fully alleged herein.

38. From in or about May 2018 and continuing to in or about March 2019, the exact dates being unknown to the Grand Jury, in the Dallas Division of the Northern District of Texas and elsewhere, **Daniel Canchola** did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud Medicare, a health care benefit program as defined in 18 U.S.C. § 24(b), and to obtain by means of materially false and fraudulent pretenses, representations, and promises in connection with the delivery of, and payment for, health care benefits, items, and services, by submitting or causing the submission, of false and fraudulent claims to Medicare for CGx tests, that were, among other things, not medically necessary and prescribed without any physician-patient relationship.

39. On or about the dates specified below, in the Dallas Division of the Northern District of Texas, and elsewhere, **Daniel Canchola**, aided and abetted by others, and aiding and abetting others known and unknown to the Grand Jury, submitted or caused to be submitted, the following false and fraudulent claims to Medicare for CGx tests that were, among other things, not medically necessary and prescribed without any physician-patient relationship, in execution of the scheme described in Paragraph 38, with each claim forming a separate count:

Count	Medicare Beneficiary	Approx. Date of Submission of Claim	Claim No.	Approx. Total Amount Billed	First Genetic Test Listed in Claim; HCPCS Code
TWO	M.B.	8/12/2018	85647481416	$16,780.00	Gene analysis (adenomatous polyposis coli), full gene sequence; 81201
THREE	B.H.	10/20/2018	79941510918	$23,968.00	Gene analysis (adenomatous polyposis coli), full gene sequence; 81201
FOUR	I.V.	12/3/2018	81184463715	$11,264.00	Gene analysis (adenomatous polyposis coli), full gene sequence; 81201

All in violation of 18 U.S.C. §§ 1347 and 2.

Forfeiture Notice
(18 U.S.C. §§ 981(a)(1)(C), 982(a)(7) and 28 U.S.C. § 2461(c))

40. Pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), upon conviction of Count One, the defendant, **Daniel Canchola,** shall forfeit to the United States, any property, real or personal, which constitutes or is derived from proceeds traceable to the violation.

41. Pursuant to 18 U.S.C. § 982(a)(7), upon conviction of Counts Two through Four, the defendant, **Daniel Canchola,** shall forfeit to the United States, any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

42. Pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), if any of the property described above, as a result of any act or omission of a defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred, sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States intends to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

A TRUE BILL

FOREPERSON

ERIN NEALY COX
UNITED STATES ATTORNEY

ROBERT ZINK
U.S. Department of Justice
Criminal Division, Fraud Section
Chief

ALLAN J. MEDINA
U.S. Department of Justice
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

THE UNITED STATES OF AMERICA

v.

DANIEL R. CANCHOLA, M.D. (01)

INDICTMENT

18 U.S.C. § 1349 (18 U.S.C. §§ 1347 and 1343)
Conspiracy to Commit Health Care Fraud and Wire Fraud
(Count 1)

18 U.S.C. §§ 1347 and 2
Health Care Fraud
(Counts 2-4)

18 U.S.C. §§ 981(a)(1)(C), 982(a)(7) and 28 U.S.C. § 2461(c)
Forfeiture Notice

4 Counts

A true bill rendered

FORT WORTH FOREPERSON

Filed in open court this 18th day of September, 2019.

Warrant to be Issued

UNITED STATES MAGISTRATE JUDGE
No Criminal Matter Pending